ABSTRACT

Thesis title: Umbilical cord mesenchymal stem cells – Systemic analysis and recommendations for research in Vietnam

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Background: Umbilical cord-derived mesenchymal stem cells (UC-MSCs) have emerged as a promising therapeutic candidate due to their favorable biological characteristics; however, global literature currently lacks multi-level systematic reviews encompassing the full spectrum from laboratory to clinical research. In the context of Vietnam, despite increasing scientific interest, research efforts remain fragmented and are primarily characterized by small-scale trials conducted without standardized protocols or unified clinical guidelines. Consequently, there is a critical absence of a systematic evidence base to inform a comprehensive strategy for the production, preclinical evaluation, and clinical application of UC-MSCs for the local infrastructure.

Objective: This study aims to conduct a multi-level systematic review across manufacturing, preclinical, and clinical stages to identify existing gaps in UC-MSC research. Ultimately, it leverages these findings to establish a foundational evidence base and propose context-appropriate recommendations for the development of stem cell therapies in Vietnam.

Methods: This study employs a systematic analysis approach conducted in strict accordance with the PRISMA 2020 guidelines. A comprehensive literature search was performed across multiple electronic databases, utilizing predefined inclusion and

exclusion criteria to ensure objectivity and minimize bias in data synthesis. Excel software was used to analyze data regarding production, preclinical and clinical data and visualize results in charts and graphs. Recommendations were generated based on the findings of systemic analysis and local context.

Results: The analysis of 68 studies plus 9 trials highlights a significant transparency gap in manufacturing, characterized by a "black box" in preclinical protocols regarding passage limits and media composition, contrasting with the higher safety compliance found in clinical trials. Furthermore, systemic delivery remains the dominant administration route in both settings, although localized injections are preferred for specific indications like osteoarthritis and myocardial infarction. While research trends have shifted from synchronized growth to a recent surge in human trials, liver diseases, type 2 diabetes, and neurological disorders emerge as the most promising indications with consistent therapeutic efficacy.

Recommendation: To address the identified "black box" in cell manufacturing, Vietnam should establish a comprehensive national regulatory framework that mandates the standardization of quality control protocols and manufacturing transparency for both preclinical and clinical research. Future research initiatives should prioritize high-efficacy therapeutic areas such as type 2 diabetes, chronic liver diseases, and neurological disorders while strategically expanding into rare or refractory conditions. Furthermore, clinical practice should transition toward a manufacturing - oriented mindset that emphasizes stringent safety assessments, including sterility and biological contaminant validation, to align with international GMP standards.